DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 18, 2017

Denver Biomedical, Inc.
% Nancy Sauer
Evergreen Research, Inc.
433 Park Point Drive, Suite 140
Golden, CO 80401

Re: K051711
Trade/Device Name: Pleurx Peritoneal Catheter Kit and Drainage Kits
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: PNG
Dated: November 2, 2005
Received: November 7, 2005

Dear Nancy Sauer:

This letter corrects our substantially equivalent letter of November 15, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051711

Device Name: Pleurx Peritoneal Catheter Kit and Drainage Kits

Indications for Use:

The Denver® Pleurx Peritoneal Catheter Kit (50-8000) is indicated for:

- Intermittent drainage of symptomatic, recurrent, malignant ascites that does not respond to medical management of the underlying disease
- Palliation of symptoms related to recurrent malignant ascites
- Peritoneal placement only

The Denver® Pleurx Drainage Kits (50-7500 and 50-7510) are indicated for use with either the Pleurx Peritoneal Catheter Kit or the Pleurx Pleural Catheter Kit.

Prescription Use _____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051711

(Posted November 13, 2003)

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510(k) Summary

Sponsor Information

Denver Biomedical, Inc.
14998 W. 6th Ave., Bldg. E700
Golden, CO 80401
303-279-7500

Contact Person: Jeff Hill, RA/QA Coordinator

This 510(k) summary was prepared on June 23, 2005 and updated November 10, 2005.

Device Identification

This special 510(k) is for a modification to the intended use of the Pleurx Catheter and Pleurx Drainage Kits.

Intended Use

The Denver Pleurx Peritoneal Catheter Kit and the Denver Pleurx Drainage Kits are indicated for

Intermittent drainage of symptomatic, recurrent, malignant ascites that does not respond to medical management of the underlying disease.

Palliation of symptoms related to recurrent malignant ascites.

For peritoneal placement only.

Device Description

The Pleurx Catheter is silicone catheter that can be thought of as containing three zones: the fenestrated zone which is implanted in the body cavity and used to collect fluid; the cuffed zone, which is placed inside a subcutaneous tunnel; and the externalized zone, which includes a valve that remains closed, except when purposefully accessed for a drainage procedure. The Pleurx Drainage Kit includes a vacuum bottle with drainage line that connects to the Pleurx catheter for removing fluid. It also includes a procedure pack that includes all the supplies needed to perform the drainage procedure and to replace the dressing over the catheter.

Substantial Equivalence to Currently Marketed Device

The sponsor used the following techniques to determine that the modified design is substantially equivalent to that of currently marketed products.

- Verifying that the design and materials are the same or similar to those of legally marketed medical devices, including the existing Pleurx Catheter and other catheters for long-term implantation in the peritoneal cavity.
- Comparing the proposed intended use to the intended use of other legally marketed devices.

- Gathering clinical data to show that the catheter is effective for removing ascites and relieving symptoms until death or ascites resolution in the majority of patients.
- Gathering clinical data to show that for most patients the duration of catheter function is at least twice as long as the interval between paracentesis procedures before catheter placement.
- Gathering clinical data to show that the complication rates associated with the use of the device for malignant ascites are similar to those for other similar devices.
- Applying risk management techniques to assess the potential impact of the change in intended use on device safety, and adopting appropriate risk control measures.